NOV 1 4 2001

510(K) SUMMARY

K013291

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**

Advanced Diagnostics Incorporated
8112 304th Avenue SE
Preston, WA 98050
Contact Person:
Steve Hesler
Director of Regulatory Affairs
phone: 425 222 7169
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Date Prepared:
9/28/01

2. **Proprietary Name:**

Altair Model DEI System (Diffractive Energy Imaging)
Common/ Usual Name:
Acoustical Holography Imaging System
Classification Name:
90 NCS

3. **Predicate Device:** K001510

The DEI System is substantially equivalent to the OS-2000 Optical Sonography system cleared via ~~k100150~~, November 30, 2000 with the addition of on-screen measurement capability with associated calculations.

4. **Device Description:**

The DEI System is a general purpose, software-controlled, diagnostic ultrasound system that complies with pre-amendment application-specific acoustic output levels (track 1). Its function is to acquire ultrasound data in acoustical holography mode and display it on an LCD monitor.

The DEI System has been designed to meet the following product safety standards:

- UL 2601 – Standard for Medical Electrical Equipment - Part 1: General Requirements for Safety
- "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", September 30, 1997.
- "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices", CDRH, 1985.

5. **Intended Uses:**

The DEI System ultrasound imaging system is intended for the following uses: Small Parts, Pediatrics, Musculoskeletal, Superficial Musculoskeletal, and Peripheral Vascular applications.

6. **Technological Comparison to Predicate Device:**

DEI System is similar to the predicate device in that both use an object transducer that is coupled to the patient by use of a water-path (immersion in water bath or use of water bladders) to transmit pulsed ultrasound through the targeted tissues. These transmitted pulses are then acoustically focused. The focused ultrasound beam is then combined

with a second plane wave (reference wave) of the same frequency as the transmit wave. The interaction of the transmit wave and the reference wave creates an interference pattern on a target detector device within the enclosed system, forming an acoustic hologram of the object. The detector is illuminated with a coherent light source (laser) resulting in a visual image. The visual image is recorded with a CCD video camera and the images are displayed on a video monitor. Images may be stored to hard disk.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

OCT 13 2012

Mr. Steve C. Hesler
Director of Quality and Regulatory Affairs
Advanced Diagnostics, Inc.
8112 304th Ave. SE, Suite B
PRESTON WA 98050

Re: K013291
Trade/Device Name: Altair Model DEI System, Diffractive Energy Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: NCS
Dated: September 28, 2001
Received: October 2, 2001

Dear Mr. Hesler:

This letter corrects our substantially equivalent letter of November 14, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part

807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely Yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

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Attachment 3

Ultrasound Device Indications Statement

510 (k) Number (if known) : ~~K001510~~ K013291

Device Name : **DEI System Optical Sonography System**

Intended Use: Diagnostic ultrasound imaging of human soft tissues

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Acoustic Holography
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Neurosurgical										P
Pediatric										P**
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										P
Peripheral vessel										
Laparoscopic										P
Musculo-skeletal Conventional										P
Musculo-skeletal Superficial										
Other (specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Other Indications or Modes: **Small parts imaging is intended for the breast

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

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